

Statistical analysis

Interim analysis

A blinded interim analysis will be performed, and assessed by a data safety monitoring board after including 50% of the required patients in each arm using O'Brien-Fleming stopping rules. This means that if the treatment is particularly beneficial or harmful compared to the control group, the investigators will be able to make a deliberate consideration of terminating the study earlier. The Fisher's exact test will be used to assess the significance of differences between both groups.

Definitive analysis

Frequencies and proportions will be calculated for categorical values. Means or medians (and standard deviations or interquartile ranges) will be calculated for continuous variables depending on normality.

The proportion of successes in each arm will be reported with 95% confidence intervals and compared using a two-sample test for proportions (Chi-square or Fisher's exact test). To quantify the effect of treatment on the outcome, a logistic regression model will be used. An odds ratio will be calculated with a 95% confidence interval. Thereafter we will conduct a secondary analysis to study the effects of variables thought to be a possible predictor of successful treatment such as maternal age, gestational age, gravidity etc.

Statistical software

Statistical analyses will be performed using SPSS version 26. (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.)